

I. Status of the Claims and Specification

Claims 1-20 are pending. Claims 1 and 2 have been amended.

Support for the claim amendments is found at pages 5-6 of the specification.

Claim 21 is new. Support is found in original claim 3.

II. Traverse of Restriction Requirement

Applicants respectfully traverse the current restriction requirement. It is respectfully pointed out that claim Groups I and II deal with a closely related class of compounds, their compositions and methods of using such compounds to treat disorders of the lower urinary tract. In fact, the compounds of claim Groups I and II are homologs. Compounds of claim Group I and Group II have a common bis aromatic left hand portion linked to piperazine by an alkyl linker. The piperazine is in both cases substituted by homologous groups at the N-1 nitrogen. In this sense, the claims in invention Groups I and II represent related aspects of a unified inventive concept and should be examined in the same patent application.

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~~Therefore, the compounds cannot fall in a separate field of search and should not~~  
present a burden for searching by the Examiner.

For the foregoing reasons, the restriction requirement is not believed to be well taken and is requested to be withdrawn.

III. Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-2 and 4-5 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The claims have been amended to address the Examiner's rejection.

Amended claim 1 now defines the term "optionally substituted" in terms of the nature and number of substituents possible. The amendments to claim 1 all find support within the specification (see pages 5-6).

The terms "aryl" and "heteroaryl" have been deleted from the claim.

The amended claims are believed to satisfy the structures of 35 U.S.C. § 112, paragraph 2.

In light of these amendments, withdrawal of the § 112 second paragraph rejection is respectfully requested.

IV. Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1-2 and 4-5 stand rejected as containing subject matter which ~~was not described in the specification in such a way as to enable one skilled in the~~ art to make and use the invention. This ground for rejection is not believed to be well taken and is respectfully traversed.

The Examiner contends the term "optionally substituted," "heteroaryl" and "aryl" reads on all such functional groups, monocyclic and polycyclic ring systems regardless of complexity of structure and lacks proper enablement within the specification.

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The optionally substituted groups have been limited in amended claim 1 to structural groups which find support within the specification. (See, for example, page 5, lines 19-21.) The aryl or heteroaryl groups Ar and Ar' have been limited to optionally substituted phenyl and pyridyl which find support within the specification. (See, for example, page 5, lines 17-19 and page 5, at lines 26-28.) Finally, the aryl or heteroaryl group B has been limited to be optionally substituted phenyl, fused oxygen containing ring systems having 6 members, and fused nitrogen containing ring systems having 5 members which find support within the specification at page 5, lines 21-25 and example 16. Support for the synthesis of the claimed compounds can be found within the specification at pages 8-14.

The present specification contains sufficient information to enable a person of ordinary skill in the art to make and use the invention defined by the amended claims. The specification provides representative compounds and examples 4-17, as well as general synthetic methods at pages 8-14 to enable ~~those skilled in the art to make and use the compounds defined by the present~~ claims.

In light of the amendments to claim 1 and the arguments presented, withdrawal of the § 112 first paragraph rejection is respectfully requested.

Claims 1-2 and 4-5 stand rejected as failing to provide reasonable assurance that representative compounds of the scope claimed will have the

requisite activity to practice the invention. This ground for the rejection is not believed to be well taken and is respectfully traversed.

The present specification contains sufficient information and assurance to enable a person of ordinary skill in the art to make and use the invention as defined by the amended claims. The specification (Table 1, page 27) provides representative compounds with the desired activity. This would provide assurance to one skilled in the art that compounds called for in the amended claims possess the requisite pharmaceutical activity.

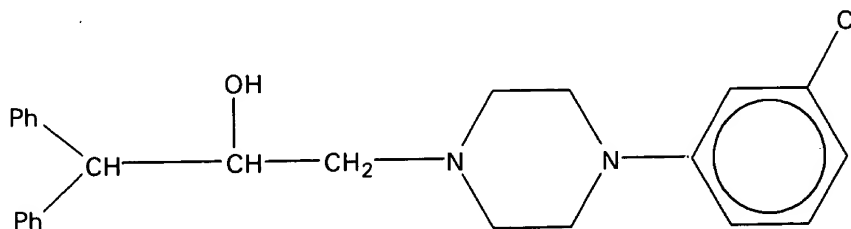
In light of the amendments to claim 1 and the arguments presented, withdrawal of the § 112, first paragraph rejection is respectfully requested.

#### IV. Rejections Under 35 U.S.C. §102(b)

Claims 1, 2, 4 and 5 stand rejected over Hagan (*Eur. J. of Pharma* 331: 169-174 (1997)). Hagan describes a compound BRL-15572, defined as 4-(3-chlorophenyl)- $\alpha$ -(diphenylmethyl)-1-piperazineethanol dichloride. The structure of this compound is not disclosed. This structure is believed to be CAS Registry

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Number 193611-72-2 shown below:



The rejection of claims 1, 2, 4 and 5 for anticipation over the Hagan reference is respectfully traversed.

Claims 1, 2, 4 and 5 call for the possibility of Y equal COH in the structure shown in claim 1. The Hagan reference shows a compound where the hydroxyl group is at a different position and therefore does not disclose a compound where Y equal COH. Withdrawal of the §102(b) anticipation rejection is respectfully requested.

Claims 1, 2, 4 and 5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kleeman (U.S. '213). This rejection is respectfully traversed.

Amended claim 1 calls for Ar and Ar' to be phenyl or pyridyl. The corresponding positions in Kleeman have Ar and Ar' equal to thiophene. Kleeman does not disclose Ar and Ar' to be phenyl and pyridyl as defined in claim 1. Withdrawal of the 102(b) rejection is respectfully requested.

V. Rejections Under 35 U.S.C. §103(a)

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~~Claims 1-5 and 19-20 stand rejected under 35 U.S.C. §103(a) over~~  
Ward (U.S. '078). The Examiner cites example 9 in Ward wherein the second Ar ring (R<sub>2</sub> in Ward Formula I) on the 3 position (A = CH<sub>2</sub>CH<sub>2</sub> in Ward Formula I) of the propyl side chain is imidazolyl. The Examiner contends that Ward teaches the interchangeability of the exemplified ring with pyridyl.

The amended claim does not include Y equal CH or COH with Ar and  
Ar' equal to optionally substituted pyridyl. Amended claim 1 also does not include

Y equal CH or CHOH with Ar equal to optionally substituted phenyl and Ar' equal to optionally substituted pyridyl. The compounds defined by the amended claims are not suggested by Ward. In Ward, when Y equal CH or COH, Ar' must be heteroaryl. In the present claims, Ar' cannot be heteroaryl when Y equal CH or COH. There is no suggestion in Ward of any compound in which Ar' is not heteroaryl when Y equal CH or COH. Accordingly, Ward does not provide any motivation to prepare the compounds of the present claims.

In light of the amendments to claim 1, withdrawal of the § 112, second paragraph rejection is respectfully requested.

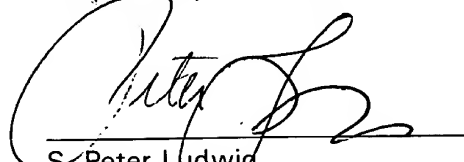
VI. Information Disclosure Statement Deficiency

Missing reference 8, page 157, is enclosed herein.

**CONCLUSION**

In view of the foregoing amendments and remarks, the present claims  
~~are believed to be in condition for passage to allowance and such action is~~  
earnestly solicited.

Respectfully submitted,

  
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